

Chapter 2:
**Methods Behind the
How-To Steps**

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To develop a system of steps toward improved health care for participants in HIV/AIDS clinical trials, we worked from findings in the Partnering for Care project, as well as experience gained from HIV prevention trials funded by USAID and the Bill & Melinda Gates Foundation and carried out by FHI and others. The complete results from the Partnering for Care project are available in *Partnering for Care in the HIV Prevention Trials Network. Part I: Overall Findings*, by Kathleen M. MacQueen, Kerry McLoughlin, Patty Alleman, Holly McClain Burke, and Natasha Mack, and *Partnering for Care in the HIV Prevention Trials Network. Part II: Case Studies*, edited by MacQueen and McLoughlin. Here, we provide an overview of the Partnering for Care project and GCM's *Mapping the Standard of Care at Microbicide Clinical Trial Sites*.

In the summer of 2004, the Partnering for Care project started with a survey. Using e-mail, MacQueen and her colleagues contacted the principal investigators and study coordinators at all 33 of the HPTN sites. This survey simply asked — “yes” or “no” — if the sites had developed any partnerships to provide care for participants in clinical trials.

In June 2005, the leaders of the Partnering for Care project sent a second survey. Only those who had responded to the first survey received the second one. In addition, the second survey only went to staff at sites with an active or pending HPTN protocol between May 2004 and May 2005. For the second survey, those who responded “no” to the first survey were asked to describe health care referral options, regulatory requirements, and any other

policies related to care for trial participants. Principal investigators and study coordinators who responded “yes” to the first survey also received a second survey, which included the questions about health care referral options, as well as a request to describe their partnerships, among other questions.

By December 2005, the Partnering for Care project collected surveys from 16 sites. Then, the study leaders consulted with a project advisory group to select sites for case studies based on four criteria:

- Unique aspects regarding referral systems, referral follow-up, or capacity building
- Geographic diversity — at least one site from Africa, Asia, Latin America, and the United States
- Adequate detail provided in the survey or from follow-up contacts by e-mail and telephone
- Willingness on the part of the site research team to be a case study

As a result of the two surveys, follow-ups, and case-study criteria, the Partnering for Care project team selected seven HPTN sites for further study (see Appendix 2 for more details on each site):

- Fiocruz, Rio de Janeiro, Brazil
- Makerere University–Johns Hopkins University (MU–JHU) Research House, Kampala, Uganda
- Medical Research Council (MRC), Durban, South Africa
- National AIDS Research Institute (NARI), Pune, India
- University of North Carolina Project (UNC Project), Tidziwe Centre, Lilongwe, Malawi
- University of Pennsylvania, Philadelphia, Pennsylvania, USA
- University of Zimbabwe–University of California, San Francisco (UZ–UCSF) Collaborative Research Programme, Harare, Zimbabwe

With the case study sites selected, project leaders turned to in-depth approaches. From March through May 2006, social science investigators from FHI — working with HPTN staff at the seven case study sites — visited the clinical trial sites, referral treatment sites, and the communities in which the trial participants lived or worked. These visits included observations of the programs and discussions with staff at the trial and referral sites, as well as talking with members of community advisory boards (CABs) where they existed. Each site visit lasted at least five days, and follow-up contacts through e-mails and telephone calls provided additional information.

From the combined information collected, the leaders of the Partnering for Care project assessed how sites develop and maintain health care for clinical trial participants both through trial staff and referrals to partners. In addition, the Partnering for Care project looked for the challenges faced in creating and maintaining effective partnerships.

This manual also relies on findings from GCM's *Mapping the Standard of Care at Microbicide Clinical Trial Sites*, which was conducted in mid-2006. This study examined the care and prevention services provided for women primarily in clinical trials of microbicides used in HIV prevention. Specifically, this GCM study evaluated six microbicide trials and one trial that studied the use of diaphragms for HIV prevention.

The GCM study included three phases. First, researchers studied documents related to the trials, including study protocols, standard operating procedures, policy documents, and staff training manuals. Second, the investigators conducted telephone interviews with study sponsors and staff, including at least one principal investigator, from each site. Last, researchers visited six trial sites in four African countries. The visits included interviews with investigators and staff, observations of clinical facilities, and assessments of local and referral care.

We can combine knowledge from this variety of studies — including the Partnering for Care project, GCM's *Mapping the Standard of Care at Microbicide Clinical Trial Sites*, and others — to assess a wide range of health care strategies during clinical trials designed for treatments that might prevent HIV.